

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

HUMAN GENOME SCIENCES, INC.,)	
)	C.A. NO. 08-166-SLR
Plaintiff,)	
)	
v.)	
)	
GENENTECH, INC.,)	
)	
Defendant.)	

**GENENTECH, INC.'S REPLY BRIEF
IN SUPPORT OF ITS MOTION TO DISMISS**

OF COUNSEL:

WEIL, GOTSHAL & MANGES LLP
Matthew D. Powers
Vernon M. Winters
201 Redwood Shores Parkway
Redwood Shores, CA 94065
(650) 802-3000

WEIL, GOTSHAL & MANGES LLP
Elizabeth Stotland Weiswasser
Peter Sandel
Rebecca Fett
767 Fifth Avenue
New York, NY 10153
(212) 310-8000

Dated: July 11, 2008

Philip A. Rovner (#3215)
POTTER ANDERSON & CORROON LLP
Hercules Plaza
P.O. Box 951
Wilmington, DE 19899
(302) 984-6000
E-mail: provner@potteranderson.com

Attorneys for Defendant
Genentech, Inc.

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I. Introduction and Summary

The interference statutes command that “[t]he Board of Patent Appeals and Interferences *shall* determine questions of priority of the inventions,” and the case law holds that the Administrative Procedures Act applies to actions by the administrative agency known as the United States Patent and Trademark Office and its Board of Patent Appeals and Interferences. Notwithstanding such law, in the interference below, plaintiff, Human Genome Sciences, Inc., made the calculated tactical decision simply to bypass the Board’s consideration of priority – unilaterally announcing, after the interference had been pending for more than two years, that plaintiff would bypass the Board and file a § 146 action in a district court. Now, seeking to avoid the result of its tactics, plaintiff advances three main arguments.

First, plaintiff proposes a new legal theory: *partial* interference exhaustion. The purpose of an interference is to determine priority, and it is divided into two phases: the Motions Phase and the Priority Phase. In the Motions Phase, the Board makes rulings that allocate the burden of proof in the Priority Phase. In the Priority Phase, the Board decides priority. Plaintiff’s new legal theory is that a party in an interference satisfies the administrative exhaustion requirement by participating only in the Motions Phase.

The law does not support plaintiff’s new theory, and neither do the policies underlying the administrative exhaustion requirements. Plaintiff’s theory would transform Board consideration of priority from a statutory command applicable to both parties into a discretionary option unilaterally exercisable by the junior party. Plaintiff’s theory would replace the existing statutory and regulatory system with a new ‘interference a la carte’ scheme allowing a party to conduct an interference only until the point when it becomes unhappy with a Board ruling – at which point the party could bypass further administrative proceedings and proceed directly to a district court to begin §146 “review.” The logical endpoint of this argument is that a party

unhappy with being designated the junior party at the beginning of the interference could file a § 146 action. Such results cannot be reconciled with the existing statutory and regulatory system.

It would also be contrary to policies underlying the existing statutory and regulatory system, one of which is efficiency. The general APA case law rejects the notion that the partial exhaustion that plaintiff proposes serves efficiency's interests, as does a common-sense reading of the interference statutes and regulatory scheme. The Board "*shall*" consider priority in the first instance precisely for reasons of efficiency: to allow all concerned, including this Court, to reap the benefit of the Board's high degree of expertise in and experience with the very technical issues in play when assessing priority.

Second, plaintiff argues (apparently in the alternative) that its failure to exhaust should be excused because, it announces, it would have been "impossible" and thus futile for plaintiff to continue with the Priority Phase in light of the Board's decisions on benefit. That argument, however, proves both too little and too much. Too little, because the case law requires that a plaintiff invoking the futility exception to the prudential exhaustion doctrine *show*, clearly and positively (not simply announce), that it would have been impossible to prove priority. Plaintiff failed to make any such *showing* to this Court. Too much, because like all allocations of the burden of proof, the Board's decision on benefit generally has a material effect on the outcome: the junior party, not the senior party, has the burden of proving priority. Under plaintiff's theory, a junior party could bypass administrative consideration of priority, if it so chose, by unilaterally declaring futility. That would transform the narrow futility exception into a broad practice; the exception (futility would generally excuse a failure to exhaust) would swallow the rule (futility only rarely excuses failure to exhaust).

Third, and finally, plaintiff asserts repeatedly that in this Court's *HGS v. Amgen* Order dismissing plaintiff's § 146 complaint against Amgen, this "Court has already grappled with and rejected the underlying premise of Genentech's argument." This Court did the opposite: in that Order, the Court confirmed the underlying premise of Genentech's argument. Invoking both prudential and jurisdictional exhaustion concepts, this Court dismissed plaintiff's § 146 complaint against Amgen for the same reasons that dismissal is warranted here – plaintiff failed to exhaust its administrative remedies.

Plaintiff's *post-hoc* attempt to avoid the consequences of its calculated attempt to bypass Board consideration of priority is not sustainable. The exhaustion requirement, for the benefit of all concerned, allows the administrative tribunal to exercise its own discretion, apply its own special expertise, and correct its own errors, thereby promoting administrative responsibility and efficiency and minimizing the frequent and deliberate flouting of administrative processes which could weaken the tribunal's effectiveness. Plaintiff made a choice below to bypass the Board's administrative process, and that choice has a legal consequence. Genentech respectfully asks that the Court dismiss plaintiff's complaint.

II. Argument

A. Prudential Exhaustion Mandates Dismissal

1. Plaintiff's New 'Partial Exhaustion' Theory Is Without Legal Support

Plaintiff's new 'partial exhaustion' argument is legally unsound. As an initial matter, the general APA case law rejects it. "Exhaustion means just that. It is not enough that plaintiff takes an initial step or steps and then abandons the process." *Jordan v. United States*, 522 F.2d 1128, 1132 (8th Cir. 1975) (citing *Aircraft & Diesel Equip. Corp. v. Hirsch*, 331 U.S. 752, 767 (1947)); Defendant's Opening Br. § IV(A) [D.I. 10]. Yet plaintiff did precisely that: it took initial steps (contested the interference through the Motions Phase) and then abandoned the

process (unilaterally announced that it would not participate in the Priority Phase, without a Board adjudication of priority). By its very terms the exhaustion doctrine mandates exhaustion of the *full* administrative process, not merely a plaintiff-selected truncation of that process.

Plaintiff seeks to avoid the general APA law by arguing administrative exhaustion law is regulatory-scheme-specific, and that no Federal Circuit cases have specifically applied an exhaustion requirement to the peculiar fact pattern created by plaintiff's attempted end-run. Plaintiff's Opposition Br. § (B)(4) [D.I. 15]. The general APA law applies to the PTO. "The PTO is an 'agency' subject to the APA's constraints." *In re Zurko*, 527 U.S. 150, 154 (1999). "The APA was meant to bring uniformity to a field full of variation and diversity" among different regulatory schemes. *Id.* at 155. It would frustrate that purpose to permit divergence from APA requirements on an agency-by-agency basis. *Id.* Yet that is what plaintiff proposes here.

Indeed, plaintiff ignores that every court that has discussed the issue has concluded that the statutory scheme underlying § 146 contains an administrative exhaustion requirement. *See* Defendant's Opening Br. § IV(C) [D.I. 10] (citing *General Motors Corp. v. R. E. Dietz*, 420 F.2d 1303 (D.C. Cir. 1969); *Human Genome Sciences, Inc., v. Amgen, Inc.*, No. 07-780-SLR, 2008 U.S. Dist. LEXIS 38464 (D. Del. May 9, 2008) ("*HGS v. Amgen* decision"); *Enzo Therapeutics, Inc. v. Yeda Research and Dev. Co.*, 477 F. Supp. 2d 699 (E.D. Va. 2007); and *Consolidated World Housewares, Inc. v. Finkle*, 662 F. Supp. 389 (N.D. Ill. 1987), *aff'd*, 829 F.2d 261 (Fed. Cir. 1987)).

Plaintiff's approach to these and other cases is either to ignore them (*General Motors*) or to misconstrue them (*HGS v Amgen*, *Enzo*, *Consolidated*, and *Rasmusson*). In attempting to distinguish this Court's *HGS v Amgen* decision, plaintiff argues that this "Court has already

grappled with and rejected the underlying premise of Genentech's argument." Plaintiff's Opposition Br. at 18 [D.I. 15]. In point of fact, this Court did the opposite: confirmed, as Genentech's motion explains, that exhaustion requirements apply to § 146 actions. Plaintiff's approach to *Enzo* is to criticize this Court's reliance on *Enzo* in its *HGS v Amgen* decision. Plaintiff's Opposition Br. at 20, n.11 [D.I. 15]. This Court, however, there correctly concluded that *Enzo* contains "helpful analysis" that "delineated the scope of its jurisdiction in terms of *exhaustion of administrative remedies*," *HGS v Amgen*, 2008 U.S. Dist. LEXIS 38464, at *20-21 (citing *Enzo*, 477 F. Supp. 2d at 710), and which points firmly away from failure to exhaust here.¹ Plaintiff does not dispute that under *Consolidated*, a § 146 plaintiff must first exhaust its administrative remedies before the PTO; plaintiff protests instead that "[u]nlike the patentee in *Consolidated*, [plaintiff] is *not* seeking to bypass the Board." Plaintiff's Opposition Br. at 24 [D.I. 15]. Plaintiff's protestation aside, that is exactly what plaintiff did below and is trying to do again here.

Invoking *Rasmusson v. SmithKline Beecham Corp.*, Int. No. 104,646 (B.P.A.I. Oct. 8, 2003) [D.I. 16, Exh. F], plaintiff asserts that its actions "have been accepted by both the Board and the courts in other cases." Plaintiff's Opposition Br. at 19 [D.I. 15]. However, this Court has already concluded that *Rasmusson* does not justify the result that plaintiff seeks to impose. As this Court explained in its *HGS v. Amgen* decision, *Rasmusson* is not analogous because it involved an appeal of an interference to the Federal Circuit under § 141, and not an action for district court review under § 146. *HGS v Amgen*, 2008 U.S. Dist. LEXIS 38464, at *24, n.10. *See Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005). This Court explained that the failure exhibited by plaintiff to adequately develop a record before the Board

¹ Unless otherwise noted, all emphasis in quotations is supplied.

would be of less concern in an appeal to the Federal Circuit under § 141, because in a district court case under § 146 there is greater “room for mischief” in light of “supplemental discovery [that] can be taken and new evidence proffered to the court.” *HGS v Amgen*, 2008 U.S. Dist. LEXIS 38464, at *24, n.10. *Rasmusson* is not relevant here for the further reason that it did not involve a deliberate bypass by an interference party of Board consideration of priority. In that case (in contrast to here) the **Board** (and not a party to the interference) had terminated the interference prior to the final hearing on priority. Here, by contrast, plaintiff concedes that the Board “was prepared to continue with a priority phase in the interference.” Plaintiff’s Opposition Br. at 23 [D.I. 15].

The result that plaintiff seeks is also inconsistent with the policies underlying the administrative exhaustion requirement. As this Court has explained, “[t]he purposes of the exhaustion requirement are to ‘promote administrative efficiency, respect executive autonomy by allowing an agency the opportunity to correct its own errors, *provide courts with the benefit of an agency’s expertise*, and serve judicial economy by having the administrative agency complete the factual record.’” *Patnaude v. Gonzales*, 478 F. Supp. 2d 643, 648 (D. Del. 2007) (Robinson, J.) (quoting *Robinson v. Dalton*, 107 F.3d 1018, 1020 (3d Cir. 1997)). Plaintiff’s approach denies, for example, the Court of the benefit of the PTO’s expertise regarding highly technical subject matter and of findings of fact and conclusions of law that normally form the basis of § 146 review. If adopted, plaintiff’s theory would allow parties simply to abandon further administrative interference procedures upon receipt of any intermediate adverse ruling with which the party disagrees. The two possible outcomes from that structure are either (a) a series of interlocutory appeals with the case shuttling back and forth between the PTO and the District Court, or (b) the case staying at the District Court for a determination of priority in the first

instance. The former would be the “deliberate flouting,” *Republic Indus., Inc. v. Central Pennsylvania Teamsters Pension Fund*, 693 F.2d 290, 293 (3d Cir. 1982), of the administrative process against which the exhaustion requirement guards. And the latter is disallowed under the statute and the case law, which preclude District Court jurisdiction to conduct an interference in the first instance. *See Consolidated World Housewares Inc. v. Finkle*, 831 F.2d 261, 265 (Fed. Cir. 1987); 35 U.S.C. § 135(a).

Lacking support in the case law, plaintiff seeks comfort in analogy. In particular, plaintiff argues repeatedly that the result it seeks is analogous to a defendant in a patent infringement case stipulating to infringement following a claim construction ruling. That analogy is not apt. Patent infringement litigation in district court is not preceded by administrative consideration of infringement and is not governed by the APA. Plaintiff’s analogy is thus a tautology, because it assumes that which it seeks to prove: that there is no administrative exhaustion requirement.

2. Plaintiff’s New ‘Partial Exhaustion’ Theory Requires a Factual Premise That Is Wrong

Plaintiff’s new ‘partial exhaustion’ theory also requires a factual premise that is wrong. Plaintiff’s factual premise is that it is seeking review *only* of the Board’s benefit decisions (and certain subsidiary issues) and that plaintiff does not seek review of a Priority Phase in which plaintiff did not participate; therefore, according to plaintiff, it exhausted its remedies because it filed motions and oppositions on those issues. Plaintiff’s Opposition Br. § (B)(2) [D.I. 15].

That factual premise is counterfactual. Plaintiff’s complaint seeks review of the Priority Phase, and indeed expressly seeks an award of priority to plaintiff and against Genentech:

WHEREFORE, HGS respectfully requests judgment that:

o. HGS is awarded priority against Genentech;

Complaint at 5, 7 [D.I. 1]. Hence the factual premise on which plaintiff's argument depends – that it exhausted its administrative remedies because it participated in the decisions on which it now says it seeks review – is wrong.

3. Plaintiff's 'Futility' Argument Proves Too Little – It Merely Asserts, Instead of (As Required) Shows

Seeking to excuse its self-selected truncation of the interference by invoking the narrow futility exception to the prudential exhaustion doctrine, plaintiff announces that it would have been “impossible” for it to win priority before the Board. Plaintiff's Opposition Br. at 12 [D.I. 15]. That announcement proves too little, and is in tension with plaintiff's own prior statements to this Court.

To invoke the narrow futility exception, “plaintiffs must *show* that it is *certain* that their claim will be denied.” *UDC Chairs Chapters v. University of the District of Columbia*, 56 F.3d 1469, 1475 (D.C. Cir. 1995). To excuse the failure to exhaust based on futility, there must be “a clear and positive showing of futility” to the Court. *Harrow v. Prudential Ins. Co. of Am.*, 279 F.3d 244, 249 (3rd Cir. 2002). Plaintiff makes no such *showing* to this Court, let alone a showing that is *clear and positive*. Instead, plaintiff simply announces futility.

The interference below involved two counts, neither of which plaintiff quotes, let alone analyzes. According to plaintiff, for it to show priority, it would have had to have shown that it (1) conceived of the inventions defined by the counts before Genentech's accorded benefit date (May 14, 1998), and (2) had exercised reasonable diligence from May 14, 1998 to May 4, 2000.

Plaintiff concedes that it had to meet these requirements. *See* Plaintiff's Opposition Br. at 13 [D.I. 15]. Accordingly, to prove futility, plaintiff would have to have shown this Court, clearly and positively, that plaintiff could not prove those two requirements.

Plaintiff's opposition, however, makes no such *showing* to this Court—indeed, it does not even try. Hence the narrow futility exception does not apply. *See, e.g., Communications Workers of Am. v. AT&T*, 40 F.3d 426, 432-33 (D.C. Cir. 1994) (reversing finding of futility because there was no *showing* that it “was a foregone conclusion” that the agency would have reached an “adverse decision”).

Apparently trying to divert from its own prior statements to this Court, plaintiff alleges that Genentech has stated that plaintiff's case on priority was “futile.” Plaintiff's Opposition Br. at 9, 17 [D.I. 15]. To the contrary, following the Motions Phase, Genentech asked the Board to direct plaintiff to show cause before the Board how plaintiff could establish priority, *i.e.*, how it could establish diligence over the nearly two-year period, as well as a prior conception. Plaintiff did not agree to do so (it skipped the Priority Phase entirely) and the Board determined to continue with the Priority Phase of the interference. Plaintiff would transform a request by Genentech that plaintiff be ordered to show how plaintiff *could* prove priority before the Board into some sort of finding, binding on this Court, that plaintiff *could not* prove priority. As elsewhere, plaintiff cites no authority for the transformation that it proposes.

Plaintiff's futility position here is also in tension with its futility position in the *HGS v. Amgen* lawsuit. In its motion for reconsideration of this Court's Order dismissing that case, plaintiff did *not* argue that trying to prove diligence over a *three-year period on the same count as one of the counts at issue here* would have been futile; instead, it argued that it would have been difficult and unlikely. [D.I. 11, Exh. 18] (proving diligence would have been, “to be

charitable, an extremely difficult endeavor”). As a matter of law, “[t]he mere fact that an adverse decision *may have been likely* does not excuse a party from a statutory or regulatory requirement that it exhaust administrative remedies.” *Corus Staal BV v. United States*, 502 F.3d 1370, 1379 (Fed. Cir. 2007). And as a matter of fact, based on plaintiff’s position in the interferences below, the diligence period here (two years) is shorter than the diligence period in *HGS v Amgen* (just over three years).² If plaintiff has previously argued that a *three*-year diligence period would *not* have been futile, why does it now argue that a *two*-year diligence period *would* be futile?

4. Plaintiff’s ‘Futility’ Argument Also Proves Too Much – It Would Generally Justify Bypassing Board Consideration of Priority

Plaintiff’s futility argument – that its unilateral declaration that the Board’s benefit decisions “defined a priority contest that HGS could not win” excuses plaintiff’s failure to exhaust (Plaintiff’s Opposition Br. § B(1)(a) [D.I. 15]) – also proves too much: if accepted, it would generally justify bypassing Board consideration of priority.

As an initial matter, any decision on interference benefit motions is simply an interlocutory ruling on the burden of proof – not, as plaintiff argues, *see* Plaintiff’s Opposition Brief at 15, a “final” decision. The relevant regulations specifically provide that “[a] decision on motions without a judgment is *not final* for purposes of judicial review.” 37 C.F.R. § 41.125. Under the PTO’s regulations, “[p]arties are presumed to have invented interfering subject matter in the order of the dates of their accorded benefit for each count”; hence the senior party is presumed to have priority. However, a junior party can overcome that presumption: “[p]riority

² See Plaintiff’s Opposition Br. at 13 [D.I. 15] (stating that HGS would have had to show diligence from just prior to Genentech’s accorded benefit date of May 14, 1998 to May 4, 2000). In the *HGS v Amgen* case, HGS stated that it would have to have shown diligence from just prior to Amgen’s accorded benefit date of February 13, 1997 to May 4, 2000. See Supplemental Declaration of Rebecca Fett, Exh. 1 (HGS’ Answering Brief in Opposition to Immunex’s Motion to Dismiss, at 6 (Case No. 07-780-SLR [D.I. 20])).

may be proved by a preponderance of the evidence except a party must prove priority by clear and convincing evidence if the date of its earliest constructive reduction to practice is after the issue date of an involved patent or the publication date under 35 U.S.C. § 122(b) of an involved application or patent.” 37 C.F.R. §§ 41.207(a). Like all allocations of the burden of proof, its allocation in an interference can and generally does make it relatively easier or harder for one of the interference parties to prove its case. Under plaintiff’s theory, however, once the Board decides the benefits motions, the losing party could simply unilaterally declare “futility,” bypass Board consideration of priority, and proceed (subject to jurisdiction and venue requirements) to the district court of its choosing to file a § 146 action.

Plaintiff’s new futility theory would turn existing futility law on its head. The futility exception is narrow. *Corus*, 502 F.3d at 1379. Under plaintiff’s approach, it would be broad: a junior party who concludes that it has a ‘bad’ priority position could invoke plaintiff’s approach and simply bypass the Board’s consideration of priority and proceed with a § 146 lawsuit. The § 146 district court would thereby be denied the benefits (for example, the application of agency expertise, and the issuance of findings of fact and conclusions of law) of the Board’s adjudication of the full administrative process. And, like plaintiff’s new exhaustion theory, plaintiff’s new futility theory would rewrite the statutory command that “[t]he Board of Patent Appeals and Interferences shall determine questions of priority of the inventions,” 35 U.S.C. § 135(a), to provide that “[t]he Board of Patent Appeals and Interferences shall may determine questions of priority of the inventions, unless the junior party chooses to bypass the Board and seek judicial review under 35 U.S.C. § 146.” It would overrule the case law that a District Court does not have jurisdiction in the first instance to conduct an interference. *Consolidated*, 831 F.2d at 265. And it would change the regulatory command that “[a] decision on motions without a

judgment is *not final* for purposes of judicial review,” 37 C.F.R. § 41.125, to provide that “[a] decision on motions without a judgment is ~~not~~ final for purposes of judicial review if the junior party chooses to bypass the Board and seek judicial review under 35 U.S.C. § 146.”

In short, plaintiff’s futility argument should be rejected both for a failure of proof and because if accepted it would effectively end Board consideration of priority. Dismissal of plaintiff’s § 146 action on prudential exhaustion grounds is appropriate here. It is also appropriate on jurisdictional exhaustion grounds, to which we now turn.

B. Dismissal On Jurisdictional Exhaustion Grounds is Appropriate

The jurisdictional exhaustion issue is whether the statute requires, as a matter of statutory construction, exhaustion of remedies. *See* Defendant’s Opening Br. § IV(B) [D.I. 10]. Dismissal on jurisdictional grounds is appropriate here because the Board is statutorily obligated to continue with the Priority Phase of an interference following the Motions Phase.

Plaintiff has made that point previously to this Court, before being served with this dismissal motion. In particular, plaintiff previously argued that “[a] *plain reading* of 35 U.S.C. § 135(a) indicates that after an interference is declared, *the Board is obligated to determine the priority of invention* . . . The Board is therefore *statutorily obligated* to continue with the priority phase.” [D.I. 11, Exh. 14 at 2]. Plaintiff’s current opposition brief does not acknowledge, let alone try to distinguish, its prior argument on this point.

Instead, plaintiff argues that “[t]he mandate that the Board ‘shall’ determine priority has absolutely nothing to do with the jurisdiction of district courts to review Board decisions, but rather, it ensures that the Board does not use § 135 to construct a regulatory scheme for *inter partes* opposition proceedings.” Plaintiff’s Opposition Br. at 26 [D.I. 15]. The legislative history plaintiff cites in support does not address, let alone support, plaintiff’s contention.

III. Alternative Arguments

A. Plaintiff's § 103 Claims Are Not Proper Here

Plaintiff's opposition ignores the fundamental premise of Genentech's motion that plaintiff's § 103 claims should be dismissed in the event this action proceeds. Plaintiff notably focuses on it having filed a motion for "invalidity" (the correct term is "unpatentability") and ignores that the sole basis for that motion was anticipation under § 102(e). Plaintiff nowhere identifies having specifically and properly raised § 103 during the underlying interference. Failure to do so precludes it being raised here. Specifically, plaintiff does not dispute that:

- Its list of proposed motions sought permission from the Board to assert unpatentability solely based on anticipation under § 102(e) and **not** under § 103;
- Other than anticipation under § 102(e), plaintiff's proposed motion list did not include any other unpatentability motions and did not mention § 103;
- Throughout the substantive motions phase of the underlying Interference, plaintiff never raised unpatentability under § 103;
- The Board confirmed that plaintiff had not sought authorization of a § 103 motion during the Motions Phase; or
- The Board's determination not to authorize the filing of motions directed to unpatentability was within its discretion.

Obviousness under § 103 is accordingly a theory of unpatentability that plaintiff did not properly raise during the interference. As explained in Genentech's opening brief, an issue is appropriate for review under § 146 only if it "was undeniably placed" before the Board. Defendant's Opening Br. at 19 [D.I. 10]. New theories of unpatentability are not permitted, even if other theories of unpatentability were alleged. *Id.* at 21-22. If this action proceeds, plaintiff's claims under § 103 should be dismissed for not having been properly raised below.

B. Plaintiff's Sanctions Claims Should Be Dismissed

In its opposition plaintiff does not identify how the complained-of conduct underlying its sanctions claims was properly before the Board, or any authority under which it would be properly before this Court. Plaintiff does not dispute that:

- The complained-of communications occurred during *ex parte* prosecution of a Genentech patent application that was not at issue in the underlying Interference;
- The challenged communications occurred long before the Interference was even declared;
- The challenged communications did not impact the patentability of either plaintiff's involved patent (plaintiff's '568 Patent issued) or Genentech's involved patent application;
- The Rule pursuant to which plaintiff sought sanctions (Board Rule 128) is limited to "Contested Cases" before the Board and that the challenged communications did not occur during a Contested Case;
- Plaintiff filed the same grievance before the OED;
- The Board exercised its discretion and concluded that the OED was better suited to address matters of potential attorney misconduct during *ex parte* examination;
- The OED reviewed the matters that plaintiff raised, and it dismissed them after finding that "no determination has been made that a violation of the U.S. Patent and Trademark Office's ('USPTO') disciplinary rules occurred"; or
- The OED decision is final and not subject to administrative review. 37 C.F.R. §11.2(d) ("A decision [by OED] dismissing a complaint or closing an investigation is not subject to review by petition.").

Plaintiff's opposition identifies no basis on which it should be permitted to keep these claims in this case. Plaintiff's opposition does no more than restate its allegations as to the challenged conduct of Genentech.³

Plaintiff asserts that Genentech "did not cooperate" with plaintiff's alleged request that

³ The opposition also materially mis-states facts. *See generally* Genentech's Opening Brief § V(B) [D.I. 10] (setting forth the facts with a supporting declaration). But the opposition cannot dispute, and does not dispute, the material facts that: (1) the Board concluded that the complained-of conduct would be better addressed to the OED; (2) the OED considered that conduct; and (3) the OED concluded that there was no basis to proceed. Plaintiff's opposition brief provides no authority that, given such facts, the sanctions claim is properly before this § 146 Court.

Genentech provide plaintiff “with Genentech’s representations to OED.” Plaintiff’s Opposition Br. at 31 [D.I. 15]. Plaintiff notably fails to provide any support for its assertion that Genentech rejected any such request – or even that plaintiff made one. That is because plaintiff never asked for such materials. Plaintiff merely requested that Genentech consent to it providing the redacted OED letter to in-house counsel – and Genentech agreed. Genentech attached this correspondence to its opening brief. [D.I. 11, Exh. 10]. Plaintiff never requested anything further from Genentech, including “Genentech’s representations to OED.” Instead plaintiff advised Genentech that despite the OED letter dismissing plaintiff’s grievance, plaintiff would not withdraw these sanctions claims. [D.I. 11, Exh. 17].

IV. Conclusion

Plaintiff failed to exhaust its administrative remedies before the PTO, and under each of the prudential exhaustion (Rule 12(b)(6)) and jurisdictional exhaustion (Rule 12(b)(1)) doctrines, dismissal is warranted – just as the Court dismissed the co-pending *HGS v. Amgen* § 146 action, again for plaintiff’s failure to exhaust administrative remedies.

In the alternative, and only if the Court does not dismiss the action, the Court should:

(1) dismiss plaintiff’s allegations of unpatentability under 35 U.S.C. § 103 (Complaint, Prayer ¶ (q)), for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1) or, if subject-matter jurisdiction is present, Fed. R. Civ. P. 12(b)(6) for failure to state a claim on which relief can be granted; and (2) dismiss plaintiff’s claims seeking or relating to sanctions (Complaint, Prayer ¶¶ (m), (n)) under Fed. R. Civ. P. 12(b)(1) or, to the extent that subject-matter jurisdiction is present, strike them under Fed. R. Civ. P. 12(f).

POTTER ANDERSON & CORROON LLP

OF COUNSEL:

WEIL, GOTSHAL & MANGES LLP

Matthew D. Powers

Vernon M. Winters

201 Redwood Shores Parkway

Redwood Shores, CA 94065

(650) 802 3000

WEIL, GOTSHAL & MANGES LLP

Elizabeth Stotland Weiswasser

Peter Sandel

Rebecca Fett

767 Fifth Avenue

New York, NY 10153

(212) 310 8000

Dated: July 11, 2008

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By: 

Philip A. Rovner (#3215)

Hercules Plaza

P.O. Box 951

Wilmington, DE 19899

(302) 984-6000

E-mail: provner@potteranderson.com

Attorneys for Defendant

Genentech Inc.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I, Philip A. Rovner, hereby certify that on July 11, 2008, the within document was filed with the Clerk of the Court using CM/ECF; that the document was served on the following party as indicated; and that the document is available for viewing and downloading from CM/ECF.

BY HAND DELIVERY AND E-MAIL

Steven J. Balick, Esq.
John G. Day, Esq.
Ashby & Geddes LLP
500 Delaware Avenue, 8th Floor
Wilmington, DE 19899
Sbalick@ashby-geddes.com
jday@ashby-geddes.com

I hereby certify that on July 11, 2008 I have sent by E-mail the foregoing document to the following non-registered participants:

Richard L. DeLucia, Esq.
John R. Kenny, Esq.
Kenyon & Kenyon
One Broadway
New York, NY 10004
rdelucia@kenyon.com
jkenny@kenyon.com

/s/ Philip A. Rovner
Philip A. Rovner (#3215)
Potter Anderson & Corroon LLP
Hercules Plaza
P. O. Box 951
Wilmington, DE 19899
(302) 984-6000
provner@potteranderson.com